K010818

MAY 2 4 2001

Tab F: 510(k) Summary of Safety and Effectiveness

Name, address, phone and fax numbers for person submitting the 510(k) notification:

Arnold Silverman, President
Skil-Care Corporation
29 Wells Avenue
Yonkers, NY 10701
Phone: 914-963-2040
Fax: 914-963-2567

Contact person: Arnold Silverman

Date summary was prepared: March 14, 2001

Device name:

Trade name:	Infant Limb Holder
Common name:	Infant Limb Holder
Classification name:	Protective Restraint

Predicate device:

Infant Limb Holder, Model # 4733, marketed by the J.T. Posey Company

Device description:

Infant Limb Holders have a 1 1/4-inch-wide by 5 1/4-inch-long cuff made of 1/4-inch-thick polyurethane foam. The foam is backed with Velcro loop material. The trade name for the cuff material (foam laminated to loop material) is "Vel-Foam" and is a standard material used by many manufacturers of limb holder devices. A 5/8-inch-wide cotton tape, 50 inches in length, is folded in half and stitched to one end of the cuff creating two ties. A tab of Velcro hook material, 5/8-inch-wide by 1 1/2-inches-long, is stitched to same end of the cuff as the cotton tape. The Velcro hook tap extend beyond the edge of the cuff and secures to the loop material on the cuff, thereby permitting a care-giver to position and secure the cuff around an infant's wrist or ankle.

Indications for use:

Infant Limb Holders are intended for infant patients who

* Disrupt medical treatment such as IVs, catheters, or wound care
* Are prone to self-injury

Comparative information:

The device submitted herein is substantially equivalent to the Infant Limb Holder, Model # 4733 legally marketed by the J.T. Posey Company.

Note:

The use of all patient restraints in nursing homes are subject to Health Care Financing Administration's regulations which prohibit the use of any physical restraint imposed for the purpose of discipline or convenience. Further, most health care facilities are accredited. HCFA rules governing appropriate use and accreditation standards for device use and personnel training provide the control necessary to ensure that the devices are used correctly. The application of these standards along with public awareness and health care provider training have contributed significantly to ensuring that the least restrictive restraint is used, that restraints are used only when needed for proper medical treatment, and that their use if under appropriate supervision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 4 2001

Mr. Arnold Silverman
President
Skil-Care Corporation
29 Wells Avenue
Yonkers, New York 10701

Re: K010818
Trade/Device Name: Infant Limb Holder, Models 306080 & 306081
Regulation Number: 880.6760
Regulatory Class: I
Product Code: FMQ
Dated: March 16, 2001
Received: March 19, 2001

Dear Mr. Silverman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known): Not known K010818

Device name: Infant Limb Holder

Indications for use:

Skil-Care Infant Limb Holders are intended for infants who:

* Disrupt medical treatment such as TVs, catheters, or wound care
* Are prone to self-injury

(Please do not write below this line - Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ -OR- Over-the counter use ___

(Optional format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010818